NOV 1 3 2000

K002520

510(K) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter: Rovers Medical Devices B.V.
Lekstraat 10
5347 KV OSS
The Netherlands
Phone +31 (0) 412 64 88 70
Fax +31 (0) 412 62 38 35

Contact Person: Mr. M.D. Zwart, President Rovers Medical Devices B.V.

USA Representative:

Todd M. Gates
Rovers Medical Devices
960 Chapea Road
Pasadena CA 91107
U.S.A
Phone: (626) 744-9171
Fax: (626) 744-9182

Device Name:

Proprietary Name: Rovers Spatula
Common/Usual Name: Cervical Cell Scraper
Classification Name: Cervical Cytological Spatula

Equivalent Device:

Rovers Cervex-Brush

Device Description:

The Rovers Spatula has a curved head similar in design to the widely used Ayre spatula, allowing easy scraping and removing of cellular material from the surface of the cervix or vagina. The spatula head is composed of polypropylene. The device is wholly disposable. To collect cervical cells, the curved blunt edge of the spatula is placed against the cervix. Digital rotation with gentle pressure by way of the handle causes the blunt edge to scrape and remove cytological material from the ectocervix. The spatula is then removed from the vagina and the cytological material is transferred to a glass slide or a preservative fluid and sent to the laboratory for evaluation.

Intendend Use Statement:

The Rovers Spatula is intended for the collection of cervical cells for analysis by Pap smear methods and/or by methods for detecting sexually transmitted disease (STD). The Rovers Spatula is not intended for use in pregnant women.

Submitter's Statement

On behalf of Rovers Medical Devices, I, Todd Gates have reviewed the premarket notification, and believe that, to the best of my knowledge, all data and information contained in the 510(K) application are truthful and accurate, and that no material fact has been omitted.

Signature: _____ Date: 11/7/00

Name: TODD M. GATES Todd M. Gates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2000

Mr. Todd M. Gates
Rovers Medical Devices B.V.
960 Chapea Road
PASADENA CA 91107

Re: K002520
Rovers Spatula
Dated: August 10, 2000
Received: August 15, 2000
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HHT

Dear Mr. Gates:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002520

Device Name: Rovers Spatula

Indications for Use:

The Rovers Spatula is intended for the collection of cervical cells for analysis by Pap smear methods and / or by methods for detecting sexually transmitted disease (STD). The Rovers Spatula is not intended for use in pregnant women.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002520

Prescription Use ✓
(Per 21 CFR 801.109)